

## EPA REGISTRATION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

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**OAT AGRIO CO., LTD.**

**EPA Company No. 11581**

**5F8408**

EPA has received a pesticide petition (5F8408) from **OAT AGRIO CO., LTD., 1-3-1 Kanda Ogawa-machi, Chiyoda-ku, Tokyo 101-0052, Japan** proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.

1. by establishing a tolerance for residues of

**Flutianil, (Z)-2-[2-fluoro-5-(trifluoromethyl)phenylthio]-2-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile, including its metabolites and degradates, in or on apple, fruit at 0.2 ppm, apple, juice at 0.03 ppm, apple, wet pomace at 2 ppm, cantaloupe at 0.07 ppm, cherry, fruit at 0.4 ppm, cucumber at 0.02 ppm, grape, fruit at 0.7 ppm, grape, juice at 0.2 ppm, grape, raisins at 0.3 ppm, squash at 0.03 ppm, and strawberry, fruit at 0.3 ppm.** EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of FDDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

### **A. Residue Chemistry**

#### **1. Plant metabolism.**

The plant metabolism of flutianil is adequately understood in four diverse crops: apple, cucumber, grape and lettuce. The parent compound, flutianil, accounted for the majority of residues extracted in all crops. The metabolism of flutianil in plants is understood for the purposes of the proposed tolerances.

#### **2. Analytical method.**

The following analytical method was used for apple, cantaloupe, cherry, cucumber, squash and strawberry samples: residues were extracted with acetonitrile/water solution and the aqueous sample was cleaned up by liquid/liquid partition with hexane. The organic phase was concentrated and further cleaned up using a silica gel column. Quantitation was achieved by GC/MSD in selective ion monitoring mode.

The lowest level of method validation (LLMV) in the apple study was 0.01 ppm. Based on recoveries of samples fortified at the LLMV, the limit of detection (LOD) and limit of quantitation (LOQ) were

calculated as 0.001 ppm and 0.0037 ppm, respectively for the apple RAC, 0.002 ppm and 0.0046 ppm for apple juice, and as 0.0003 ppm and 0.00076 ppm, respectively, for apple wet pomace.

The LLMV in the cantaloupe study was 0.010 ppm. Based on recoveries of samples fortified at the LLMV, the LOD and LOQ were calculated as 0.001 ppm and 0.0038 ppm, respectively.

For the cherry study, the LLMV was 0.010 ppm.

Based on recoveries of samples fortified at the LLMV, the LOD and LOQ were calculated as 0.0009 ppm and 0.0027 ppm, respectively in the cucumber study. The LLMV in the cucumber study was 0.01 ppm.

In the squash study, the LLMV in this study was 0.01 ppm. Based on recoveries of samples fortified at the LLMV, LOD and LOQ were calculated as 0.001 ppm and 0.0030 ppm, respectively.

The LOD was determined to be 0.0025 ppm for strawberry, and the LOQ was 0.0076 ppm. The LLMV was 0.010 ppm for strawberry.

In the grape RAC and PC study, the analytical method was as follows: flutianil residues were analyzed and quantified in grapes, grape juice and raisins by gas chromatography after extraction and cleanup. Flutianil metabolite OC-56635 residues were analyzed and quantified in grapes, grape juice and raisins by high performance liquid chromatography with tandem mass spectral detection (LCMS/MS). A LOQ of 0.01 mg/kg was determined for flutianil and OC-56635 in grapes and grape juice. A LOQ of 0.10 mg/kg was determined for flutianil and OC-56635 in raisins. The limit of detection was set at 30% of the LOQ.

### **3. Magnitude of residues.**

#### **Apple**

Foliar applications of flutianil (V-10118, a 5EC formulation) at a rate of approximately 0.04 lb ai/A each were made 4 times (~7 day retreatment interval), for a total of approximately 0.16 lb ai/A in the apple magnitude of residues study. The results from the trials show that the maximum residues in/on apple were 0.095 ppm. V-10118 was also applied at 5X the application rate (approximately 0.2 lb ai/A) at three sites to provide apples for processing into juice and wet pomace. The results from the trials show that the maximum residues in/on apple juice to be 0.016 ppm and wet pomace to be 1 ppm.

#### **Cantaloupe**

For cantaloupes, foliar applications of V-10118 at a rate of approximately 0.04 lb ai/A each were made 5 times (~7 day retreatment interval), for a total of approximately 0.20 lb ai/A. The results from the trials show that the maximum residues in/on cantaloupe were 0.042 ppm.

#### **Cherry**

Foliar applications of V-10118 at a rate of approximately 0.04 lb ai/A each were made 4 times (~7 day retreatment interval), for a total of approximately 0.16 lb ai/A for cherry. Five applications were made at the Washington site for a total of approximately 0.20 lb ai/A due to a delay in crop maturity. The results from the trials show that the maximum residues in/on cherry were 0.26 ppm.

#### **Cucumber**

For cucumbers, six trials were conducted in the field and two trials were conducted in the greenhouse.

Foliar applications of V-10118 at a rate of approximately 0.04 lb ai/A each were made 5 times (~7 day retreatment interval), for a total of approximately 0.20 lb ai/A. The maximum residues in/on cucumber were 0.014 ppm.

### **Grape**

Foliar applications of flutianil at a rate of approximately 0.09 lb ai/ha each were made 5 times (~7 day retreatment interval), for a total of approximately 0.49 lb ai/ha in the grape residue study. Flutianil residues in treated grape samples ranged from <LOQ to 0.4977 ppm. OC-56635 residues in treated grape samples ranged from <LOQ to 0.0536 ppm. For grape raisins and juice, flutianil was also applied at 5X the application rate (approximately 0.49 lb ai/ha per application) at one site to provide grapes for processing into juice and raisins. Flutianil residues in grape juice were found with a maximum residue of 0.2059 ppm. Flutianil residues in raisins were found with a maximum residue of 0.2993 ppm. OC-56635 residues in grape juice were found with a maximum residue of 0.0187 ppm. OC-56635 residues in raisins were found with a maximum residue of <LOQ.

### **Squash**

For squash (summer), the trials were conducted foliar applications of V-10118 at a rate of approximately 0.04 lb ai/A each were made 5 times (~7 day retreatment interval), for a total of approximately 0.20 lb ai/A. The results from the trials show that the maximum residue in/on summer squash is 0.021 ppm.

### **Strawberry**

For strawberries, trials foliar applications of V-10118 at a rate of approximately 0.04 lb ai/A each were made 5 times (~7 day retreatment interval), for a total of approximately 0.20 lb ai/A. At the Florida trial, one additional application was needed to allow the fruit to ripen for a total of approximately 0.24 lb ai/A. At the Colorado trial, two additional applications were needed to obtain fruit for harvest for a total of approximately 0.28 lb ai/A. The results from the trials show that the maximum residues in/on strawberry were 0.24 ppm.

## **B. Toxicological Profile**

### **1. Acute toxicity.**

Technical flutianil shows low acute toxicity (Toxicity Category IV) via the oral, dermal and inhalation routes of exposure. Flutianil has a very low acute oral (LD<sub>50</sub>: >5,000 mg/kg bw), dermal (LD<sub>50</sub>: >5,000 mg/kg bw) and inhalation toxicity (LC<sub>50</sub>: >5.17 mg/L air) in male and female rats. Flutianil shows no irritation to the eye or skin and shows no skin sensitization potential under the conditions of the guinea pig maximization test. There were no acute neurotoxicity concerns.

### **2. Genotoxicity.**

Flutianil was tested for its genotoxic potential in a battery of four *in vitro* or *in vivo* studies covering all required end-points (gene mutations, chromosomal aberrations). There was no evidence of genotoxicity.

### **3. Reproductive and developmental toxicity.**

Flutianil shows no evidence of primary developmental or reproductive effects. In the prenatal developmental toxicity studies in rats and rabbits and in the two-generation reproduction study in rats, neither fetal toxicity nor maternal toxicity was present. There was no evidence to suggest that Flutianil

possessed a teratogenic potential in either species.

#### **4. Subchronic toxicity.**

The subchronic toxicity of Flutianil was investigated in 90-day toxicity studies via the oral route in mouse, rat and dog and via inhalation and dermal routes in 28-day toxicity studies in the rat. Rats, dogs, and mice tolerated the chemical in excess of the limit dose without mortalities or clinical signs. The NOAEL for oral studies were 1387 mg/kg, 1271 mg/kg, and 1000 mg/kg in mouse, rat and dog respectively. The NOEL in the rat for dermal exposure was >1000 mg/kg and for inhalation was 14.4 mg/kg (100 mg/m<sup>3</sup>).

#### **5. Chronic toxicity.**

The chronic toxicity of Flutianil was evaluated in the dog, rat, and mouse. Oncogenic potential was evaluated in rats and mice. The NOAEL from the one-year feeding study in the dog was 1000 mg/kg bw/day. The NOAEL for the rat was 249 mg/kg, the highest dose evaluated. The NOAEL in the oncogenic mouse study was 1063 mg/kg bw/day. No flutianil induced carcinogenicity was observed. Flutianil is not likely to be carcinogenic, based on rat and mouse bioassays as well as negative *in vivo* and *in vitro* mutagenic effects.

#### **6. Animal metabolism.**

The elimination of flutianil was very rapid with over 90% being eliminated in the first 24 hours with little absorbed material. Absorption of [<sup>14</sup>C]-flutianil was low and biotransformation of absorbed radioactivity was rapid, giving rise to an extensive range and number of metabolites. The number and nature of metabolites and difference in radio-profiles for animals dosed with [trifluoromethyl-<sup>14</sup>C] and [2-methoxyphenyl-U-<sup>14</sup>C] labelled flutianil suggested that cleavage of the molecule was a significant process in the metabolic pathway. This was observed in both the rat and goat metabolism studies.

#### **7. Metabolite toxicology.**

One major soil metabolite was evaluated in a 28-day study which showed a NOAEL of 1380 mg/kg, which was similar to parent flutianil. Mutagenicity testing (*in vitro* bacterial reverse mutation and mouse lymphoma gene mutation and *in vivo* mouse micronucleus) was conducted with three major metabolites and all were negative.

#### **8. Endocrine disruption.**

The toxicology database for Flutianil is current and complete. Studies in this database include evaluation of the potential effects on reproduction and development and an evaluation of the pathology of the endocrine organs following short- or long-term exposure. No endocrine disruption is expected to be present following exposure to Flutianil.

#### **9. Immunotoxicity.**

Flutianil was evaluated in a 28-day dietary immunotoxicity study. The NOEL was greater than 1251 mg/kg. There was no effect on immune function.

### **B. Toxicological Endpoints**

A summary of the toxicological endpoints for flutianil used for human risk assessment is shown in the following table:

Doses and Toxicological Endpoints for Flutianil			
Exposure/Scenario	Dose Used in Risk Assessment, Interspecies, Intraspecies and any Traditional UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (females 13-49 years of age)	Not selected	NA	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Acute Dietary (General population including infants and children)	Not selected	NA	No toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Chronic Dietary (All populations)	NOAEL = 249 mg/kg/day UF = 100 Chronic RfD = 2.49 mg/kg/day	FQPA SF = 1x cPAD = Chronic RfD	Combined Chronic Toxicity/ Carcinogenicity Study in Rat (MRID No. 49490550) LOAEL = Not identified NOAEL male: 249 mg/kg
Incidental Oral Short-Term (1 – 30 days)	NOAEL = 1000 mg/kg/day UF = 100	LOC for MOE = 100	Developmental Toxicity in Rabbit (MRID No. 49490545) LOAEL = Not identified NOAEL = 1000 mg/kg
Incidental Oral Intermediate-Term (1 - 6 months)	NOAEL = 1271 mg/kg/day UF = 100	LOC for MOE = 100	Subchronic Oral Toxicity in Rat (MRID No. 49490537) LOAEL = Not identified NOAEL 1271 mg/kg
Dermal (All durations)	NA	NA	No systemic toxicity was identified in the dermal 28-day study; Highest Dose Tested was 1,000 mg/kg/day.
Inhalation (All durations)	NOAEL = 14.4 mg/kg/day UF = 100	LOC for MOE = 100 Residential LOC for MOE = 100 Occupational	28-Day Inhalation Toxicity in Rat (MRID No. 49490541) LOAEL = 1000 mg/m <sup>3</sup> based on organ weight changes and histopathological changes in liver and thyroid. (144 mg/kg conversion)
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be carcinogenic in humans."		

UF = uncertainty factor, FQPA SF = any additional safety factor retained due to concerns unique to the FQPA, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

## C. Exposure Assessment

### 1. Dietary Exposure

#### a. Acute exposure

Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute risk

assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified.

**b. Chronic exposure**

A chronic dietary risk assessment was conducted for flutianil use on apple, cantaloupe, cherry, cucumber, grape, squash and strawberry at the proposed tolerances using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 4.02) which uses food translations based on EPA/USDA FCID recipe set as of August 2014. The chronic dietary risk estimates are below HED's level of concern for the general U.S. population and all population subgroups. The most highly exposed population subgroups (0.1% of the RfD) were children 1-2 years old and children 3-5 years old.

**Summary of Chronic Dietary (Food + Drinking Water) Exposure and Risk for Flutianil**

Population Subgroup	Exposure (mg/kg bw/day)	Percent of RfD <sup>1</sup>
US population	0.000414	0.0%
All infants ( < 1 year old)	0.000901	0.0%
<i>Children (1-2 years old)</i>	<i>0.002257</i>	<i>0.1%</i>
<i>Children (3-5 years old)</i>	<i>0.001446</i>	<i>0.1%</i>
Children (6-12 years old)	0.000642	0.0%
Youth (13-19 years old)	0.000239	0.0%
Adults (20-49 years old)	0.000243	0.0%
Adults (50+ years old)	0.000304	0.8%
Females (13-49 years old)	0.000272	0.0%

<sup>1</sup> RfD = 2.49 mg/kg/day

**c. Cancer**

In accordance with the EPA Final Guidelines for Carcinogen Risk Assessment, flutianil may be classified as “Not likely to be carcinogenic in humans” and is not expected to pose a cancer risk to humans. Animal evidence demonstrates the lack of carcinogenic effects in both sexes in well-designed and well-conducted studies in rats and mice.

**2. Non-dietary exposure**

**a. Occupational exposure**

Flutianil is formulated a 5% emulsifiable concentrate to be applied to strawberry, cantaloupe, cucumber, summer squash, apple, cherry, and grape using groundboom or airblast spray equipment. The potential exposures and associated risks for handlers mixing, loading and applying flutianil and for workers re-entering treated areas are based on the proposed label for GATTEN® fungicide (flutianil 5% liquid formulation). The maximum application rate is 0.04 lb ai/acre. A maximum of four to five applications are allowed per year, depending upon crop, with a 7-day application interval.

Short- and intermediate-term dermal and inhalation exposures are predicted for occupational handlers mixing, loading, and applying flutianil. Since flutianil-specific exposure data are not available, handler scenarios were assessed using the EPA Occupational Pesticide Handler Unit Exposure Surrogate Reference

Table - Revised March 2013. The occupational handler exposure and risk estimates for flutianil are listed below.

Occupational Handler Exposure & Risk Estimates for Flutianil					
Short- & Intermediate-Term Exposure	Unit Exposure <sup>1</sup> (mg/lb ai handled)	Application Rate (lb ai/A)	Units Treated <sup>2</sup> (A/day)	Average Daily Dose <sup>3</sup> (mg ai/kg bw/day)	Short- & Intermediate-Term MOE <sup>4</sup>
<b>Mixer/Loader – Liquids – Open Loading for Airblast Application</b>					
Dermal	0.0376	0.04	40	0.000158	8,000,000
Inhalation	0.000219	0.04	40	0.00000438	3,300,000
<b>Mixer/Loader – Liquids – Open Loading for Groundboom Application</b>					
Dermal	0.0376	0.04	80	0.000316	4,000,000
Inhalation	0.000219	0.04	80	0.00000876	1,600,000
<b>Applicator – Liquids – Airblast</b>					
Dermal	1.59	0.04	40	0.00668	190,000
Inhalation	0.00471	0.04	40	0.0000942	150,000
<b>Applicator – Liquids – Groundboom</b>					
Dermal	0.0161	0.04	80	0.000135	9,400,000
Inhalation	0.00471	0.04	80	0.000188	76,000

<sup>1</sup> Unit Exposure (UE) = mg ai/lb ai handled from Occupational Pesticide Handler Unit Exposure Surrogate Reference Table - Revised March 2013. PPE = long-sleeve shirt, long pants, socks, shoes, gloves.

<sup>2</sup> Units Treated taken from Science Advisory Council for Exposure, Standard Operating Procedure 9.1, Standard Values for Daily Acres Treated in Agriculture, Rev. 25, September 2001.

<sup>3</sup> Average Daily Dose (ADD) = Unit Exposure x Application Rate x Units Treated x Absorption Factor ÷ Body Weight (80 kg). Dermal absorption factor = 21%, inhalation absorption factor = 100%.

<sup>4</sup> Margin of Exposure (MOE) = NOAEL (mg/kg/day) ÷ ADD (mg/kg/day); NOAEL<sub>dermal</sub> = 1271 mg/kg/day, NOAEL<sub>inhalation</sub> = 14.4 mg/kg/day for all durations.

Short- and intermediate-term dermal exposures are predicted for post-application exposure to workers performing typical agricultural tasks. Since flutianil-specific exposure data are not available, post-application scenarios were assessed using Science Advisory Council for Exposure (ExpoSAC) Policy 3 – Revised March 2013. The occupational post-application exposure and risk estimates for flutianil are listed below.

Occupational Post-Application Exposure & Risk Estimates for Flutianil					
Short- & Intermediate-Term Exposure	Crop Activity	Transfer Coefficient <sup>1</sup> (cm <sup>2</sup> /hr)	Application Rate (lb ai/A)	Average Daily Dose <sup>2</sup> (mg ai/kg bw/day)	Short- & Intermediate-Term MOE <sup>3</sup>
Dermal	Strawberry Hand Harvest	1,100	0.04	0.0026	490,000
Dermal	Cantaloupe, Cucumber, Summer Squash Hand Set Irrigation	1,900	0.04	0.0045	280,000
Dermal	Apple, Cherry Thinning Fruit	3,600	0.04	0.0085	150,000
Dermal	Grapes Tying/Training,	10,100	0.04	0.024	53,000



Occupational Post-Application Exposure & Risk Estimates for Flutianil					
Short- & Intermediate-Term Exposure	Crop Activity	Transfer Coefficient <sup>1</sup> (cm <sup>2</sup> /hr)	Application Rate (lb ai/A)	Average Daily Dose <sup>2</sup> (mg ai/kg bw/day)	Short- & Intermediate-Term MOE <sup>3</sup>
	Hand Harvest, Leaf Pulling				

<sup>1</sup> Transfer Coefficient from Science Advisory Council for Exposure (ExpoSAC) Policy 3 – Revised March 2013. PPE = long-sleeve shirt, long pants, socks, shoes.

<sup>3</sup> Average Daily Dose (ADD) = Transfer Coefficient (TC) x Dislodgeable Foliar Residue (DFR) x Duration \* Absorption Factor ÷ Body Weight (80 kg). DFR = 25% \* Application Rate, Duration = 8 hrs/day, Dermal Absorption Factor = 21%.

<sup>4</sup> Margin of Exposure (MOE) = NOAEL (mg/kg/day) ÷ ADD (mg/kg/day); NOAEL<sub>dermal</sub> = 1271 mg/kg/day for all durations.

All occupational handler and post-application exposures from agricultural applications of flutianil result in MOEs greater than 100 and therefore do not exceed HED's level of concern.

#### **b. Residential (Non-occupational) exposure and risk**

There are no proposed uses of flutianil which would lead to direct exposure to resident, either through mixing, loading and application, or due to post application exposure; however, there are potential indirect post-application exposures to adults and children due to drift onto residential lawns from agricultural applications. These indirect post-application scenarios were assessed based on the proposed label for GATTEN® fungicide (flutianil 5% liquid formulation) using draft Residential Exposure Assessment Standard Operating Procedures - Addenda 1: Consideration of Spray Drift (November 1, 2013). The greatest indirect residential exposure potential is from groundboom application to cantaloupe, cucumber, summer squash or strawberries. The residential post-application exposure and risk estimates for flutianil are listed below.

Residential Exposure & Risk Estimates for Flutianil				
Short- & Intermediate-Term Exposure	Lifestage	Drift Application Rate <sup>1</sup> (lb ai/A)	Average Daily Dose <sup>2</sup> (mg ai/kg bw/day)	Short- & Intermediate-Term MOE <sup>3</sup>
<b>High Contact Lawn</b>				
Dermal	Adult	0.0075	0.00059	2,200,000
Dermal	1 to <2 years	0.0075	0.0012	1,100,000
<b>Hand-to-Mouth</b>				
Incidental Oral	1 to <2 years	0.0075	0.00011	11,000,000
<b>Object-to-Mouth</b>				
Incidental Oral	1 to <2 years	0.0075	0.0000035	370,000,000
<b>Soil Ingestion</b>				
Incidental Oral	1 to <2 years	0.0075	0.00000025	5,000,000,000

#### **D. Cumulative Effects**

Cumulative effects from substances with a common mechanism of toxicity: Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”



Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flutianil and any other substances, and flutianil does not appear to produce a toxic metabolite produced by other substances. Therefore for the purposes of this tolerance action, EPA has not assumed that flutianil has a common mechanism of toxicity with other substances.

#### **E. Safety Factor for Infants and Children**

In general, Section 408 of the FFDCA provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Prenatal developmental toxicity studies in rabbits and rats showed no qualitative/qualitative evidence of increased susceptibility in offspring. The 2-generation reproduction study in rats did not show evidence of qualitative/qualitative evidence of increased susceptibility in offspring.

The toxicology database for flutianil is complete. The data are sufficient for endpoint selection for exposure/risk assessment scenarios and for evaluation of the requirements under the Food Quality Protection Act (FQPA). Evidence of quantitative and qualitative susceptibility of offspring was not observed, and therefore, the FQPA 10x safety factor was reduced to 1x.

#### **F. Aggregate Risks and Determination of Safety**

The proposed uses are the first uses proposed for flutianil in the United States.

##### **1. Acute risk**

An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified. Therefore, acute risk from flutianil exposure to is not expected.

##### **2. Chronic risk**

Using the exposure assumptions described in this unit for chronic exposure, it was concluded that exposure to flutianil from food and water will utilize 0.0% of the RfD for the U.S. population, and 0.1% of the RfD for children 1-2 years old and children 3-5 years old, the subpopulations at greatest exposure. Based on the use pattern, chronic residential exposure to residues of flutianil is not expected. Therefore, the aggregate exposure is not expected to exceed 100% of the RfD.

##### **3. Short-term risk**

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. There are no proposed uses of flutianil which would lead to direct exposure to resident, either through mixing, loading and application or due to post application exposure; however, there are potential indirect post-application exposures to adults and children due to drift onto residential lawns from

agricultural applications. Short-term aggregate exposure is not expected to exceed the Agency's level of concern.

#### **4. Intermediate-term risk**

Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water. Intermediate-term aggregate exposure is not expected to exceed the Agency's level of concern.

#### **Cancer risk**

Flutianil should be classified as, "Not likely to be carcinogenic in humans." Flutianil is not expected to pose a cancer risk.

#### **5. Determination of safety**

Based on these risk assessments, it is concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to flutianil residues.

#### **G. International Tolerances**

Tolerances have been established in Japan for the following crops: eggplant (0.2 ppm), cucumber (including gherkin (0.2 ppm)), pumpkin (including squash (0.05 ppm)), watermelon (0.05 ppm), melons (0.05 ppm) and strawberry (0.5 ppm). Tolerances have been established in Korea for the following crops: green and red pepper (0.5 ppm), strawberry (0.3 ppm), melon (0.05 ppm), watermelon (0.05 ppm), cucumber (0.05 ppm), Korean melon (0.05 ppm) and sweet pepper (0.5 ppm).